

12-14-04

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DOCKET NO. CARP0007-101

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: King and Chapman

Confirmation No. 4275

Serial No.: 10/731,759

Art Unit: 1645

Filing Date: December 8, 2003

Examiner: Not Yet Assigned

For: MONOVALENT ANTIBODY FRAGMENTS

Customer No.: 34133

EXPRESS MAIL NO.: EL964 552 828US
DATE OF DEPOSIT: December 13, 2004

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
 - ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

or

- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☒ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of non-U.S. Patent references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

EXCEPT THAT:

- ☐ In view of the voluminous nature of references **@@**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☒ Copies of references **AA-CB** listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in prior application **Serial No. 09/214,251**, filed on **March 10, 1999, abandoned**.
- ☒ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Pursuant to Fed. Reg. Vol. 69, No. 182, dated September 21, 2004, copies of U.S. Patents and U.S. Patent Publications need not be submitted as part of an Information Disclosure Statement.

Statement under 37 C.F.R. § 1.704(d)

- ☐ The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

Petition

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$_____. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

There are no listed references, which are not in the English language.

Respectfully submitted,

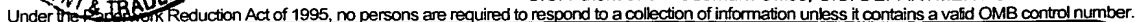
Dated:

December 13, 2004

Doreen Yatko Trujillo

Doreen Yatko Trujillo
Registration No. 35,719

COZEN O'CONNOR, P.C.
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Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

(Use as many sheets as necessary)

Sheet

1

of

6

Complete if Known

Application Number

10/731,759

Filing Date

December 8, 2003

First Named Inventor

David J. King et al.

Art Unit

1645

Examiner Name

Not Yet Assigned

Attorney Docket Number

CARP0007-101

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner
Signature

Date _____

Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Application Number	10/731,759
Filing Date	December 8, 2003
First Named Inventor	David J. King et al.
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	CARP0007-101

(Use as many sheets as necessary)

Sheet	2	of	6
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[illegible]

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ – Number ⁴ - Kind Code ⁵ (if known)				
	AL	EP 0 392 376 A2	10/17/1990	American Cyanamid Company		Yes
	AM	EP 0 392 745 B1	10/17/1990	American Cyanamid Company		Yes
	AN	WO 86/01533	03/13/1986	Celltech Limited		Yes
	AO	WO 89/01476	02/23/1989	Celltech Limited		Yes
	AP	WO 89/01974	03/09/1989	Celltech Limited		Yes
	AQ	WO 90/09195	08/23/1990	Celltech Limited		Yes
	AR	WO 91/09967	07/11/1991	Celltech Limited		Yes
	AS	WO 92/01059	01/23/1992	Celltech Limited		Yes
	AT	WO 92/22583	12/23/1992	Celltech Limited		Yes

Date
Considered

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Substitute for form 1449A/PTO				Complete if Known	
<h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 10px 0 0 0;">(Use as many sheets as necessary)</p>				Application Number	10/731,759
				Filing Date	December 8, 2003
				First Named Inventor	David J. King et al.
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	3	of	6	Attorney Docket Number	CARP0007-101

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **4** of **6****Complete if Known**

Application Number	10/731,759
Filing Date	December 8, 2003
First Named Inventor	David J. King et al.
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	CARP0007-101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AW	ABRAHAM, R., ET AL., "Screening and kinetic analysis of recombinant anti-CEA antibody fragments," <i>J. Immunol. Methods</i> , 183:119-125, (1995)	
	AX	ABUCHOWSKI, A., ET AL., "Alteration of Immunological Properties of Bovine Serum Albumin by Covalent Attachment of Polyethylene Glycol," <i>J. Biol. Chem.</i> , 252(11):3578-3581, (1977)	
	AY	ABUCHOWSKI, A., ET AL., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase," <i>J. Biol. Chem.</i> , 252(11):3582-3586, (1977)	
	AZ	AMIT, A.G., ET AL., "Three-Dimensional Structure of an Antigen-Antibody Complex at 2.8 Å Resolution," <i>Science</i> , 233:747-753, (1986)	
	BA	BENHAR, I., ET AL., "Mutations of Two lysine Residues in the CDR Loops of a Recombinant Immunotoxin That Reduce Its Sensitivity to Chemical Derivatization," <i>Bioconjugate Chem.</i> , 5:321-326, (1994)	
	BB	BOWIE, J.U., ET AL., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> , 247:1306-1310, (1990)	
	BC	BURGESS, W.H., ET AL., "Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue," <i>J. of Cell Biol.</i> , 111:2129-2138, (1990)	
	BD	CHISWELL, D.J., ET AL., "Phage antibodies: will new 'coliclonal' antibodies replace monoclonal antibodies," <i>J. Tibtech.</i> , 10:80-84, (1992)	
	BE	DELGADO, C., ET AL., "Enhanced tumour specificity of an anti-carcinoembryonic antigen Fab' fragment by poly(ethylene glycol) (PEG) modification," <i>Br. J. Cancer</i> , 73:175-182, (1996)	
	BF	FRANCIS, G.E., ET AL., "PEG-Modified Proteins in Stability of Protein Pharmaceuticals: <i>In Vivo</i> Pathways of Degradation and Strategies for Protein Stabilization," Ahern, T.J. et al. (eds.), Plenum, New York, Chapter 8, 235-263, (1991)	
	BG	GOODSON, R.J., ET AL., "Site-Directed Pegylation of Recombinant Interleukin-2 at its Glycosylation Site," <i>Bio Technol.</i> , 8:343-346, (1990)	

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **5** of **6****Complete if Known**

Application Number	10/731,759
Filing Date	December 8, 2003
First Named Inventor	David J. King et al.
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	CARP0007-101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BH	HERSHFIELD, M.S., ET AL., "Use of site-directed mutagenesis to enhance the epitope-shielding effect of covalent modification of proteins with polyethylene glycol," <i>Proc. Natl. Acad. Sci. USA</i> , 88:7185-7189, (1991)	
	BI	JANEWAY, C.A., ET AL., "Structure of the Antibody Molecule and the Immunoglobulin Genes," <i>Immuno. Biology</i> , 4 th Edition, Elsevier Science Ltd., London/Garland Publishing, New York, 82-83, (1999)	
	BJ	KENNY, J.W., ET AL., "Cross-Linking of Ribosomes Using 2-Iminoethanol (Methyl 4-Mercaptobutyrimidate) and Identification of Cross-Linked Proteins by Diagonal Polyacrylamide/Sodium Dodecyl Sulfate Gel Electrophoresis," <i>Methods in Enzymology</i> , 59:534-550, (1979)	
	BK	KITAMURA, K., ET AL., "Chemical Engineering of the Monoclonal Antibody A7 by Polyethylene Glycol for Targeting Cancer Chemotherapy," <i>Cancer Res.</i> , 51:4310-4315, (1991)	
	BL	KUAN, C-T, ET AL., "Pseudomonas Exotoxin A Mutants: Replacement of Surface Exposed Residues in Domain II with Cysteine Residues that can be Modified with Polyethylene Glycol in a Site-Specific Manner," <i>J. Biol. Chem.</i> , 269(10):7610-7616, (1994)	
	BM	LAZAR, E, ET AL., "Transforming Growth Factor α : Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities," <i>Molecular and Cellular Biology</i> , 8:1247-1252, (1988)	
	BN	LING, T.G.I., ET AL., "A General Study of the Binding and Separation in Partition Affinity Ligand Assay, Immunoassay of β_2 -Microglobulin," <i>J. Immunol. Methods</i> , 59:327-337, (1983)	
	BO	LYONS, A., ET AL., "Site-specific attachment to recombinant antibodies via introduced surface cysteine residues," <i>Prot. Eng.</i> , 3:703-708, (1990)	
	BP	MORPURGO, M., ET AL., "Preparation and Characterization of Poly(ethylene glycol) Vinyl Sulfone," <i>Bioconjugate Chem.</i> , 7:363-368, (1996)	
	BQ	NUCCI, M., ET AL., "The therapeutic value of poly(ethylene glycol)-modified proteins," <i>Adv. Drug Delivery Revs.</i> , 6:133-151, (1991)	
	BR	PANKA, D.J., ET AL., "Variable region framework differences result in decreased or increased affinity of variant anti-digoxin antibodies," <i>Proc. Natl. Acad. Sci. USA</i> , 85:3080-3084, (1988)	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

6

of

6

Complete if Known

Application Number	10/766,718
Filing Date	January 27, 2004
First Named Inventor	Charles E. Hart et al.
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	CELL0001-106

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BS	PEDLEY, R.B., ET AL., "The potential for enhanced tumour localization by poly(ethylene glycol) modification of anti-CEA antibody," <i>Br. J. of Cancer</i> , 70:1126-1130, (1994)	
	BT	RUDIHOFF, S., ET AL., "Single amino acid substitution altering antigen-binding specificity," <i>J. Proc. Natl. Acad. Sci. USA</i> , 79:1979-1983, (1982)	
	BU	SANDIE and MICHAELSEN, "Engineering the Hinge Region to Optimize Complement-induced Cytolysis," <i>Antibody Engineering, Borrebaeck (Ed.)</i> , W.H. Freeman and Company, New York, including p. 71, (1992)	
	BV	TAO and MORRISON, "Studies of Aglycosylated Chimeric Mouse-Human IgG," <i>J. of Immunol.</i> , 143:2595-2601, (1989)	
	BW	TURNER, A., ET AL., "Comparative biodistributions of indium-111-labelled macrocycle chimeric B72.3 antibody conjugates in tumour-bearing mice," <i>Br. J. Cancer</i> , 70:35-41, (1994)	
	BX	WILKINSON, I., ET AL., "Tolerogenic polyethylene glycol derivatives of xenogeneic monoclonal immunoglobulins," <i>Immunol. Lett.</i> , 15:17-22, (1987)	
	BY	WOGHIREN, C., ET AL., "Protected Thiol-Polyethylene Glycol: A New Activated Polymer for Reversible Protein Modification," <i>Bioconjugate Chem.</i> , 4:314-318, (1993)	
	BZ	ZALIPSY, S., ET AL., "Use of Functionalized Poly(Ethylene Glycol)s for Modification of Polypeptides," in <i>Poly(ethylene glycol) Chemistry: Biotechnical and Biomedical Applications</i> , Harris, J.M. (ed.), New York, Chapter 21, pp. 347-370 (1992)	
	CA	ZAPATA, ET AL., "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a single-Sulphydryl Human FAB," <i>FASEB J.</i> , 9:A1479 (1995)	
	CB	PCT International Search Report dated April 8, 1998 for International Application No. PCT/GB1997/03400, International Filing Date: October 12, 1997	

Examiner
SignatureDate
Considered

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